CLAIMS

What is claimed is:

1. A composition for coating the surface of a medical device with a bioactive agent in a manner that permits the coated surface to release the bioactive agent over time when implanted *in vivo*, the composition comprising a bioactive agent in combination with a plurality of polymers, including a first polymer component comprising at least one poly(alkyl)(meth)acrylate and a second polymer component comprising poly(ethylene-co-vinyl acetate).

2. A composition according to claim 1 wherein the device is one that undergoes flexion and/or expansion in the course of implantation or use *in vivo*.

3. A composition according to claim 1 wherein the composition permits the amount and rate of release of agent(s) from the medical device to be controlled by adjusting the relative types and/or concentrations of polymers in the mixture.

4. A composition according to claim 1 wherein the first polymer component is selected from the group consisting of poly(alkyl)(meth)acrylates with alkyl chain lengths from 2 to 8 carbons.

5. A composition according to claim 4 wherein the first polymer component has a molecular weight of from 50 kilodaltons to 900 kilodaltons.

6. A composition according to claim 5 wherein the first polymer component comprises poly n-butylmethacrylate.

7. A composition according to claim 1 wherein the second polymer component is selected from the group consisting of poly(ethylene-co-vinyl acetate) polymers having vinyl acetate concentrations of between about 10% and about 50% by weight.

8. A composition according to claim 7 wherein the vinyl acetate concentrations are between about 24% and about 36% by weight.

9. A composition according to claim 8 wherein the vinyl acetate concentrations are between about 30% and about 34% by weight.

10. A composition according to claim 1 wherein the composition comprises a mixture of poly(n-butylmethacrylate) and poly(ethylene-*co*-vinyl acetate).

11. A composition according to claim 10 wherein the total combined concentrations of both polymers in the coating composition is between about 0.25% and about 70% by weight.

12. A composition according to claim 10 wherein the poly(n-butylmethacrylate) has a molecular weight of from 100 kilodaltons to 900 kilodaltons and the poly(ethylene-*co*-vinyl acetate) provides a vinyl acetate content of from 24% to 36% by weight.

13. A composition according to claim 12 wherein the poly(n-butylmethacrylate) has a molecular weight of from 200 kilodaltons to 400 kilodaltons and the poly(ethylene-*co*-vinyl acetate) provides a vinyl acetate content of from 30% to 34% by weight.

14. A composition according to claim 1 wherein the composition further comprises a solvent in which the polymers form a true solution.

15. A composition according to claim 1 wherein the bioactive agent is dissolved or suspended in the coating mixture at a concentration of 0.01% to 90% by weight.

16. A composition according to claim 15 wherein the bioactive agent is selected from the group consisting of thrombin inhibitors, antithrombogenic agents, thrombolytic agents,

fibrinolytic agents, vasospasm inhibitors, calcium channel blockers, vasodilators, antihypertensive agents, antimicrobial agents, antibiotics, inhibitors of surface glycoprotein receptors, antiplatelet agents, antimitotics, microtubule inhibitors, anti secretory agents, actin inhibitors, remodeling inhibitors, antisense nucleotides, anti metabolites, antiproliferatives, anticancer chemotherapeutic agents, anti-inflammatory steroid or non-steroidal anti-inflammatory agents, immunosuppressive agents, growth hormone antagonists, growth factors, dopamine agonists, radiotherapeutic agents, peptides, proteins, enzymes, extracellular matrix components, inhibitors, free radical scavengers, chelators, antioxidants, anti polymerases, antiviral agents, photodynamic therapy agents, and gene therapy agents.

17. A composition according to claim 1 wherein the device is one that undergoes flexion and/or expansion in the course of implantation or use *in vivo*, the composition permits the amount and rate of release of agent(s) from the medical device to be controlled by adjusting the relative types and/or concentrations of polymers in the mixture.

18. A composition according to claim 17 wherein the first polymer component is selected from the group consisting of poly(alkyl)(meth)acrylates with alkyl chain lengths from 2 to 8 carbons, and the second polymer component is selected from the group consisting of poly(ethylene-co-vinyl acetate) polymers having vinyl acetate concentrations of between about 10% and about 50% by weight.

19. A composition according to claim 18 wherein the total combined concentrations of both polymers in the coating composition is between about 0.25% and about 70% by weight, and the composition further comprises a solvent in which the polymers form a true solution.

20. A composition according to claim 19 wherein the poly(n-butylmethacrylate) has a molecular weight of from 100 kilodaltons to 900 kilodaltons and the poly(ethylene-*co*-vinyl

acetate) provides a vinyl acetate content of from 24% to 36% by weight, and the bioactive agent is dissolved or suspended in the coating mixture at a concentration of 0.01% to 90% by weight.

21. A combination comprising a medical device coated with a composition according to claim 1.

22. A combination according to claim 21 wherein the device is one that undergoes flexion and/or expansion in the course of implantation or use *in vivo*.

23. A combination according to claim 22 wherein the first polymer component is selected from the group consisting of poly(alkyl)(meth)acrylates with alkyl chain lengths from 2 to 8 carbons, and the second polymer component is selected from the group consisting of poly(ethylene-co-vinyl acetate) polymers having vinyl acetate concentrations of between about 10% and about 50% by weight.

24. A combination according to claim 23 wherein the composition comprises a mixture of poly(n-butylmethacrylate) and poly(ethylene-*co*-vinyl acetate).

25. A combination according to claim 24 wherein the total combined concentrations of both polymers in the coating composition is between about 0.25% and about 70% by weight, and the bioactive agent is dissolved or suspended in the coating mixture at a concentration of 0.01% to 90% by weight.

26. A combination according to claim 22 wherein the medical device undergoes flexion or expansion by being bent by at least 45 degrees or more and/or expanded to more than twice its initial dimension, either in the course of its placement, or thereafter in the course of its use *in vivo*.

27. A combination according to claim 21 wherein the device is selected from the group consisting of catheters and stents.

28. A combination according to claim 26 wherein the catheter is selected from the group consisting of urinary catheters and intravenous catheters.

29. A combination according to claim 21 wherein the weight of the coating attributable to the bioactive agent is in the range of about 0.05 mg to about 10 mg of bioactive agent per cm^2 of the gross surface area of the device.

30. A combination according to claim 29 wherein the weight of the coating attributable to the bioactive agent is between about 1 mg and about 5 mg of bioactive agent per cm^2 of the gross surface area of the device, and the coating thickness of the composition is in the range of about 5 micrometers to about 100 micrometers.

31. A method of preparing a combination according to claim 21, the method comprising the steps of providing a composition according to claim 1 and applying the composition to the medical device.

32. A method according to claim 31 wherein the coating is provided by dipping or spraying the device with the composition.

33. A method according to claim 32 wherein the coating composition includes a solvent and the coating upon the device is cured by evaporation of the solvent.

34. A method according to claim 31 wherein the device is one that undergoes flexion and/or expansion in the course of implantation or use *in vivo*.

35. A method according to claim 34 wherein the first polymer component is selected from the group consisting of poly(alkyl)(meth)acrylates with alkyl chain lengths from 2 to 8 carbons, and the second polymer component is selected from the group consisting of poly(ethylene-co-vinyl acetate) polymers having vinyl acetate concentrations of between about 10% and about 50% by weight.

36. A method according to claim 35 wherein the composition comprises a mixture of poly(n-butylmethacrylate) and poly(ethylene-*co*-vinyl acetate).

37. A method according to claim 35 wherein the total combined concentrations of both polymers in the coating composition is between about 0.25% and about 70% by weight.

38. A method according to claim 37 wherein the bioactive agent is dissolved or suspended in the coating mixture at a concentration of 0.01% to 90% by weight.

39. A method according to claim 31 wherein the weight of the coating attributable to the bioactive agent is in the range of about 0.05 mg to about 10 mg of bioactive agent per cm^2 of the gross surface area of the device.

40. A method according to claim 39 wherein the weight of the coating attributable to the bioactive agent is between about 1 mg and about 5 mg of bioactive agent per cm^2 of the gross surface area of the device, and the coating thickness of the composition is in the range of about 5 micrometers to about 100 micrometers.

41. A method of using a combination of claim 21, the method comprising the steps of a) implanting the device *in vivo* under conditions in which the device undergoes flexion or expansion by being bent by at least 45 degrees or more and/or expanded to more than twice its initial dimension, either in the course of its placement, or thereafter in the course of its use *in vivo*, and b) permitting the device to remain implanted and to release the bioactive agent *in situ*.

42. A method according to claim 41 wherein the composition comprises a mixture of poly(n-butylmethacrylate) and poly(ethylene-*co*-vinyl acetate).

43. A method according to claim 41 wherein the device is selected from the group consisting of catheters and stents.

44. A method according to claim 43 wherein the catheter is selected from the group consisting of urinary catheters and intravenous catheters.

45. A method according to claim 41 wherein the weight of the coating attributable to the bioactive agent is in the range of about 0.05 mg to about 10 mg of bioactive agent per cm^2 of the gross surface area of the device and the coating thickness of the composition is in the range of about 5 micrometers to about 100 micrometers.

46. A system comprising a coated device combination according to claim 21 positioned *in situ* within a body.

47. A system according to claim 46 wherein the device is one that undergoes flexion and/or expansion in the course of implantation or use *in vivo*.

48. A system according to claim 46 wherein the composition comprises a mixture of poly(n-butylmethacrylate) and poly(ethylene-*co*-vinyl acetate).

49. A method according to claim 46 wherein the device is selected from the group consisting of catheters and stents.

50. A system according to claim 46 wherein the weight of the coating attributable to the bioactive agent is in the range of about 0.05 mg to about 10 mg of bioactive agent per cm^2 of the gross surface area of the device, and the coating thickness of the composition is in the range of about 5 micrometers to about 100 micrometers.